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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/516,598   | 12/03/2004  | Jun Kubota           | 389.44528X00        | 8546             |
| 20457 7590 10/20/2009<br>ANTONELLI, TERRY, STOUT & KRAUS, LLP<br>1300 NORTH SEVENTEENTH STREET<br>SUITE 1800<br>ARLINGTON, VA 22209-3873 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| SHAHRESTANI, NASIR   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 3737   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
| 10/20/2009   |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/516,598

**Applicant(s)**

KUBOTA ET AL.

**Examiner**

NASIR SHAHRESTANI

**Art Unit**

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-7, 9-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-6, and 11-16, and 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa et al (JP 2000060857) in view of Ophir et al (Elastographic Imaging, Ultrasound in Medicine and Biology, Vol 26, supplement 1, pp. s23-s29, 2000) and further in view of Sarvazyan (U.S. 5,524,636).

Miwa et al. discloses an ultrasound probe (31), a first image production means (tomogram, see abstract), an image display (display part 4; see also Figure 5a), at least one piece

of reference information (13), a second image (Figure 5b), and a variation operation (2AL, see Figure 5b). Miwa et al does not explicitly disclose a distortion operation or displaying of distortion information.

Ophir et al discloses a distortion operation (local axial strain, p. s27, column 1, Equation 1), based on the comparison of a locus of points in a region of interest (temporal windows, p. s27, column 1 ) in the two images, and display of distortion information (Figures 1-4). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Miwa et al to include a distortion operation and display of distortion information because the latter information allows the detection of cancerous tumors and/or lesions that are stiffer than their surroundings and are either too small, or not echogenic enough, or too deep, to be detected by conventional B-scan ultrasound or • palpation techniques. The above motivation to combine is taught by Ophir et al (p. s23, column 1).

Miwa et al does not disclose displaying distortion information at the deepest part of the image. Ophir et al further discloses displaying distortion information at the deepest part of the image (bottom of Figure 3). It would have been obvious to a person having ordinary skill in the art at the time of the invention to use the method of Miwa et al to display the distortion information at the deepest part of the image because palpation is least effective at detecting tumors and/or lesions at larger depths.

Miwa et al further discloses automatically determining appropriate imaging parameters (automatic judging of the hardness, p. 7, line 10), at a predetermined portion (organization, p. 7, line 10) of the image.

Miwa et al discloses a method of ultrasonic imaging comprising an ultrasound probe (31), a first image production means (tomogram, see abstract) using said probe in contact to a subject in a first state (before pressurization, see abstract), an image display (display part 4; see also Figure 5a), at least one piece of reference information (13), a second image (Figure 5b) obtained by bringing said probe into contact with a subject in a second state different from said first state (after pressurization, see abstract), and a variation operation (2AL, see Figure 5b). Miwa et al does not explicitly disclose a distortion operation or displaying of distortion information. Ophir et al discloses a distortion operation (local axial strain, p. s27, column 1, Equation 1), based on the comparison of a locus of points in a region of interest (temporal windows, p. s27, column 1) in the two images, and display of distortion information (Figures 1-4). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Miwa et al to include a distortion operation and display of distortion information because the latter information allows the detection of cancerous tumors and/or lesions that are stiffer (i.e. undergo less strain) than their surroundings and are either too small, or not echogenic enough, or too deep, to be detected by conventional B-scan ultrasound or palpation techniques. The above motivation to combine is taught by Ophir et al (p. s23, column 1).

Miwa et al does not disclose displaying distortion information at the deepest part of the image. Ophir et al further discloses displaying distortion information at the deepest part of the image (bottom of Figure 3). It would have been obvious to a person having ordinary skill in the art at the time of the invention to use the method of Miwa et al to display the distortion information at the deepest part of the image because palpation is least effective at detecting tumors and/or lesions at larger depths.

Miwa et al further discloses automatically determining appropriate imaging parameters (automatic judging of the hardness, p. 7, line 10), at a predetermined portion (organization, p. 7, line 10) of the image.

Miwa et al. in view of Ophir et al. do not specifically teach means for setting feature points as a reference to calculate a change of distance between feature points between a first image and second image, and eventual display of such information.

Sarvazyan et al. teach deforming of tissue relative to a reference position (see abstract) and calculation of change in modulus of tissue elasticity of a tissue portion along selected planes by imaging tissue particles and tagging tissue particles and determining shifting of particles (calculate change of distance) after deformation (see claim 7).

It would have been obvious to one ordinary skill in the art at the time of invention to have modified Miwa et al. in view of Ophir et al. and to have included the teaching of Sarvazyan et al. in order to provide for calculation of change between reference points from a first image to a second image, which would lead to the eventual presentation of such change to a user.

**Claims 7 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa et al (JP 2000/060857) in view of Ophir et al (Elastographic Imaging, Ultrasound in Medicine and Biology, Vol 26, supplement 1, pp. s23-s29, 2000) and Sarvazyan (U.S. 5,524,636) as applied to claim 1 above, and further in view of Chen et al (US 7,050,610).

The Miwa et al in view of Ophir et al and Sarvazyan teach all the elements of the claimed invention except that it does not explicitly disclose displaying a different color or shape.

Chen et al discloses color scale imaging in the context of strain imaging (column 1, lines 21-22).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the Miwa et al in view of Ophir et al. and Sarvazyan et al. and to use a color display as taught by Chen et al in order to obtain a clearer visualization of the strain field, as is well known in the art.

**Claims 9 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa et al (JP 2000060857) in view of Ophir et al (Elastographic Imaging, Ultrasound in Medicine and Biology, Vol 26, supplement 1, pp. \$23-\$29, 2000) and Sarvazyan et al. (U.S. 5,524,636) as applied to claim 1 above, and further in view of Yamashita et al (Ultrasonic Characterization of Tissue Hardness in the in-vivo Human Liver, 1994 IEEE Ultrasonics Symposium, 1449-1453).

Miwa et al in view of Ophir et al. and Sarvazyan disclose all the elements of the claimed invention except that it does not explicitly disclose calculating or graphing tissue displacement.

Yamashita et al disclose calculating and graphing the distribution of tissue displacement (Figure 2c; see also abstract) as well as character strings indicating the displacement values (Figure 2c). Yamashita et al and Miwa et al are analogous art because both are in the field of ultrasonic elastography.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to include the graph of tissue displacement with the invention of Miwa et al because the displacement information is used to calculate the strain information. Displaying the displacement information gives an additional perspective to the tissue parameters to that

provided by the strain distribution and, furthermore, the displacement information can be used as a check on the strain display to indicate possible errors or inaccuracies or ranges of validity in the latter. For example, in Figure 5c of Yamashita et al, the strain calculation will clearly not be valid for horizontal distances less than approximately 10 mm or greater than approximately 65 mm because of the abrupt changes in displacement at those points.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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